January 15, 1999

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

61/OPP#

HARTZ

THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688
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December 17, 1998

Demson Fuller/Mark Wilhite (PM-51)
Reregistration Branch RB1
Special Review and Reregistration Division
Environmental Protection Agency
Crystal Mall II
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Dear Mr. Fuller/Mr. Wilhite:

Re: Tetrachlorvinphos HED Human Health Risk Assessment
Chemical ID No. 083701, List A Reregistration Case No. 0321

This letter is in response to your letter of November 10, 1998 (transmitted to Hartz on November 18) in which you provide 30 days for our comment on the EPA Office of Pesticide Program's preliminary human health risk assessment for the organophosphate (OP) Tetrachlorvinphos (TCVP). In accordance with your instructions, we are providing a material listing of errors and omissions found in the risk assessment documents. While this listing may not be complete or comprehensive, it demonstrates that there are multiple, significant errors in terms of mathematical computation and numerous omissions of product specific data in the EPA exposure calculations. In addition, there are many errors that we have noted in terms of interpretation and use of the data in the risk assessments, some stemming from the omission of much data within the Agency's files. As per your instruction, those interpretation corrections will be provided during the 60-day public comment period, and thus do not appear here.

Since we understand that it is the intent of the Agency to make their preliminary risk assessment document available to the public via Internet without any changes, we believe that this response should accompany the EPA document so that the public will be fully informed concerning all the information in this case.

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In response to your request that, in addition to errors, we also inform you during the 30-day initial response period of any pertinent studies and sources of information on TCVP, we are herein providing a listing of studies and information which currently exist in EPA files but which do not appear to have been referenced during the preparation of this risk assessment. These studies contain data which will enable EPA to greatly refine the risk assessment to more accurately reflect actual dosage and exposure rates. If it would be helpful to EPA, we will provide copies of the referenced data.

In addition to the data already in EPA files, during the 60-day public comment period we will also provide related information and new studies about consumer use patterns and product specific application rates which bear directly upon product exposure and the resultant risk assessments.

The following is the information which is being submitted as part of this 30-day comment period.

Listing of errors and omissions in the EPA preliminary human health risk assessment

ERRORS

Mathematical errors occur in most of the tables in the TCVP Occupational and Residential Exposureand Risk Assessment (Susan Hanley, Memorandum of 11/3/98). These errors occur as a result of transposition of numbers, decimal errors, transcription errors and for other unknown reasons. An area of specific confusion is the reporting of application rates. The values given cannot be related to either the product sizes reported in Table 15, on page 11 of the report, or to the concentrations given on page 4. Examples of the mathematical errors include:

- Table 9B. Column "Absorbed Dose with Additional PPE (mg/kg/day) –Inhalation". Row "IXa-Backpack". Incorrect number for dose.
- Table 9B. Column "Absorbed Dose with Additional PPE (mg/kg/day) – Inhalation". Row "IXb-Backpack, double layer clothes...". Incorrect number for dose.
- Table 11. Column "Mixer/Loader/Applicator – LADD (mg/kg/day)". Row "Wettable Powder (IIIa) – 26 days/365 days/yr". Incorrect number for LADD.
- Table 12. Column "Total Daily Dose (mg/kg/day)". Row "IIIb". Incorrect number for daily dose.

- Table 12. Column "LADD (mg/kg/day)". Row "IIIb". Incorrect numbers for LADDs.

- Table 12. Column "Carcinogenic Risk. Row "IIIb". Incorrect numbers for risk.

- Table 12. Column "Amortization". Row "VIIb and VIIc". Numbers of treatments vary from what is reported in Table 10.

- Table 12. Column "LADD (mg/kg/day) and Carcinogenic Risk". Row "VIIb and VIIc. If the numbers of treatment days are incorrect as specified in the previous comment, then the numbers for LADDs and risks are also incorrect.

- Table 15. Column "Carcinogenic Risk". Row "Dip – 1 gallon". Incorrect numbers for risks.

- Table 15. Column "LADD (mg/kg/day)". Row "Spray Can, Entire Can, 5 days/365 days/yr, 20/70". Incorrect number for LADD.

- Table 15. Column "LADD (mg/kg/day)". Row "Dust, Half the Container, 5 days/365 days/yr, 20/70". Incorrect number for LADD.

- Table 15. Column "LADD (mg/kg/day)". Row "Pump sprays, Horse, 26 days/365 days/yr, 20/70". Incorrect number for LADD.

- Table 17. Column "Aerosol Spray (entire can)". Row "Day 0". Incorrect number for dermal dose.

- Table 17. Column "Aerosol Spray (half can)". Row "Day 1". Incorrect number for dermal dose.

- Table 18. Column "Handler Risk". Row "Dip (4 gallons)". Incorrect number for handler risk and consequently total risk.

- Table 18. Column "Handler Risk". Row "Dip (4 gallons) and Powder (entire container)". Incorrect number for handler risk and total risk for dip.

- Table 18. Column "Handler Risk". Row "Dip (4 gallons) and Spray pump (dog, one-half bottle)". Incorrect number for handler risk and total risk for dip.

- Table 18. Column "Handler Risk". Row "Spray pump (dog) (one-half bottle) and Powder (entire container)". Handler risks reversed, consequently total risk is incorrect.

- Table 18. Column "Handler Risk". Row "Aerosol (Entire can) and Collar (dog)". Incorrect numbers for handler risk, consequently total risk is incorrect.

OMISSIONS

EPA has determined that their chief concerns are with the post-application residential scenarios, relevant to the short and intermediate non-cancer exposures resulting from contact with treated pets and hand-to-mouth activity of small children. In the EPA assessment, it is noted that "no chemical-specific data were used." In fact, EPA has received numerous reports on this chemical specifically, which provide real data to substitute for the assumptions elected by EPA. Those data are contained in EPA files from reports and information previously submitted to EPA as follows.

- Weight Loss Study of Rabon Release from 2-in-1 Collars Prepared with Four Alternate Plasticizers (MRID# 43290301). This provides information on the amount of active ingredient released over time and the availability of the active ingredient overall.

- The Effect of Submersion in Water on the Bloom Rate of the Hartz 2-in-1 Collar (Submitted to the EPA on January 14, 1975). This provides information on the amount of active ingredient available in the presence of moisture.

- Stirofos (SD 8447) Hair Content in Dogs Following Exposure to the 10% Stirofos Flea Collar (Accession No. 00117364). This provides information on the removability of the active ingredient from pet fur.

- Wipe and weigh cumulative active ingredient release rates of the TCVP collar which were submitted to the EPA in a letter dated April 5, 1978. This provides information on the amount of active ingredient released over time and the availability of the active ingredient overall.

- Domestic Animal Safety Cholinesterase Test – Dogs, Test No. 1073 (MRID # 418101-02). This provides cholinesterase inhibition information in dogs and evidence of the lack of acute effects. Further it provides data on concentrations used in dip treatments.

- Domestic Animal Safety Cholinesterase Test – Cats, Test No. 1077 (MRID #418101-01). This provides cholinesterase inhibition information and evidence of the lack of acute effects in cats. Further it provides data on concentrations used in dip treatments.

- Hartz Mountain Repellent Study Test No 1157 Pump Spray (MRID # 42614101). This provides use, efficacy and dosage data for pump sprays for dogs with different hair length and weight.

- Hartz Mountain Repellent Study Test No 1167 Pump Spray (MRID # 42614102) This provides use, efficacy and dosage data for pump sprays for cats.

- Comparison of the Tick and Flea Control Efficacy of 5% Sevin with Three Rabon Insecticide Dog Dusts (Submitted to the EPA on February 22, 1979) . This study provides data on use rates and dosage ranges that achieve efficacy of control in dogs of different weights and with different hair lengths.

- Product Labels for all products. These provide information about the application rates, treatment scenarios and delivery/release profiles.

Studies which will be provided to EPA before the end of the 60-day comment period

As previously stated, during the 60-day public comment period, we will submit additional pertinent information and studies which are not currently in EPA's files. This information contains realistic measurements of exposure to applicators and handlers. The information includes, but is not limited to, the following.

- Hartz Mountain short term insecticide study by Sharp Veterinary Research. This study provides data on the concentrations in dips used for efficacious treatment.

- Hartz Mountain Short Term Efficacy Study on Cats – Pump Spray. This study provides data on the duration of product activity (therefore duration of residue) on cat hair, and on the dosage delivered in pump spray products for cats with different hair lengths and body weights.

- Hartz Mountain Short Term Efficacy Study on Dogs – Test No. 1165 – Pump Spray. This study provides data on the duration of product activity (therefore duration of residue) on dog hair, and on the dosage delivered in pump spray products for cats with different hair lengths and body weights.

- Comparison of the Tick and Flea Control Efficacy of 5% Sevin with Three Rabon Insecticide Dog Dusts. This study provides data on use rates and dosage ranges that achieve efficacy of control in dogs of different weights and with different hair lengths.

- Serum Cholinesterase Evaluation of Dogs and Cats Treated with Hartz 2 in 1 Flea and Tick Powder (containing tetrachlorvinphos). This provides data on the cholinesterase consequences from dosages of the product applied to dogs and cats.

- 85-Day Flea Powder Test on Cats. This provides data on the dose/effect relationship of the tetrachlorvinphos product on cats. Further, it provides information concerning the lack of cholinesterase depression in relation to the use of the product.

- Evaluation of a 3% Tetrachlorvinphos Powder Versus Fleas on Cats. This provides data on the dosage of tetrachlorvinphos powder used on cats and the duration of efficacy (residue on hair parameters).

- Evaluation of the Effectiveness of Flea Powder Formulations Containing Tetrachlorvinphos on Dogs. This provides data on the dosage of tetrachlorvinphos production formulas on dogs and the duration of efficacy.

- Hartz Mountain Repellent Study – Cats Test 1239. This study provides data on the dosage of the products on cats of different weight and hair length.

- Hartz Mountain Repellent Study – Dogs Test 1238. This study provides data on the dosage of the products on dogs of different weight and hair length.

- Hartz Mountain Short Term Efficacy Study on Cats – Aerosol. This study provides data on the dosage of the products on cats of different weight and hair length.

- Hartz Mountain Short Term Efficacy Study on Dogs—Aerosol. This study provides data on the dosage of the products on dogs of different weight and hair length.

Taken together, the errors, omissions and misunderstandings in the preliminary human health risk assessment presented by OPP, yield profoundly exaggerated and invalid exposure and risk values. Before the end of the 60-day public comment period, Hartz will present a comprehensive discussion of the components of the risk assessment (hazard, safety factors and exposure) and the application of data and assumptions to each of these components. That document will demonstrate that the Hartz products containing TCVP present no unacceptable, acute, intermediate or chronic risk, alone or in aggregate with other uses, as required in the Food Quality Protection Act of 1996.

One of the attachments to your November 10 letter of transmittal of the preliminary human health risk assessment (Addendum to the HED Human Health Risk Assessment and RED Chapter, from Christina Swartz, dated 11/2/98) states that in "a summary of incident reports associated with tetrachlorvinphos usage .... relatively few incidents have been reported, and there were no regulatory recommendations on the basis of these few incidents." We believe that the information which currently exists in EPA files, together with the information which we will submit during the 60-day public comment period, will confirm the fact which has been demonstrated during the twenty-five (25) year history of consumer use of TCVP based products - namely, that these products are safe for residential household use.

Hartz stands ready to meet with and work with the Agency in an interactive process to correct and refine the preliminary risk assessment prior to any publication. However, if this is not possible, as previously stated, we request that this response be placed on the Public Docket, on the internet, or in any other form of publication, in conjunction with the Agency's preliminary risk assessment in order to allow the public to be properly informed about the data which has, or will, be provided to EPA to better refine the Assessment. To facilitate your ability to include our comments and listing of errors, this information is being provided to you in both paper and electronic format.

Thank you for your attention to our comments. We look forward to your further response.

Sincerely,

Pat Bieler, Director
Government Relations